IN THE UNITED STATES PATENT & TRADEMARK OFFICE

ART UNIT:

EXAMINER: Jennifer L. Hornberger

3637

FIRST NAMED

INVENTOR: Earl C. Downey

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FOR:

SURGICAL INSTRUMENT WITH

TRIGGER CONTROL

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,

Marla E. Howlett

<u>DECLARATION OF W. BRADFORD ROCKWELL, MD</u> <u>UNDER 37 C.F.R. §1.132</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

I, W. BRADFORD ROCKWELL declare as follows:

- 1. I hold a BA from Harvard University in Cambridge, MA, and an MD from Washington University in St. Louis, MO. I completed a general surgery residency at Washington University in St. Louis, MO, a plastic surgery residency at the University of Rochester in Rochester NY, and a hand surgery fellowship at the University of Rochester in Rochester, NY.
- 2. I am Board Certified by the American Board of Plastic Surgery and the National Board of Medical Examiners, a fellow of the American College of Surgeons, and a member of the American Burn Association, the American Society of Plastic Surgeons and the Plastic Surgery Research Council. I have practiced medicine for seventeen years.
- 3. I currently serve as Chief of the Division of Plastic Surgery at the University of Utah Health Sciences Center.

- 4. I have no specific financial or professional interest, other than academic interest, in the above pending patent application, nor will I derive any personal or professional benefit from its acceptance.
- 5. Exhibit A, attached hereto, is a curriculum vitae listing some of my accomplishments, qualifications, and publications.
- 6. I recently reviewed the pending United States Patent Application No.10/551,363 to Dr. Earl C. Downey, and entitled "Surgical Instrument With Trigger Control."
- 7. As one having skill in the art, it is my understanding that the phrase "functional position" used to describe the position of the user's hand when grasping the ergonomic handle, as found on page 3, line 14 and throughout the written description, and as further illustrated in FIG. 1, has recognizable meaning as a particular hand position that is taught in the medical arts. Specifically, the functional or basic position of the hand occurs when the wrist is slightly extended in a neutral orientation, the proximal and interphalangeal joints (e.g. the lower and middle finger segments) are in 30-50 degrees of downward flexion with the distal interphalangeal joints (finger tips) being slightly extended. The thumb is held in opposition to the fingers in a relaxed manner. The fingers are slightly separated at 5-10 degrees.
- 8. As one having skill in the art, it is my opinion that the ergonomic handle of the Downey surgical instrument comprises structure permitting operation of the instrument with the hand of the user in a position consistent with the functional position, and imparting the best ergonomic configuration. The wrist is in 5-10 degrees of extension. The proximal and interphalangeal joints of the middle, ring and little fingers are in or near 30-50 degrees of downward flexion as the palm and fingers of the hand wrap around the grip portion, while the thumb is positioned about the upper portion in a relaxed orientation opposite the fingers. This position frees the index finger to individually extend and contract to operate the finger receiving portion of the finger actuator and allows the application of maximal force with maximal comfort while minimizing the potential for joint stress and nerve injury, especially with the portions of the hand grasping the ergonomic handle.
- 9. I also recently reviewed United States Patent No. 6,074,408 to Freeman, entitled "Modular Medial Instrument and Method of Using the Same."
- 10. As one having skill in the art, it is also my opinion that the medical instrument of Freeman, as illustrated in FIG. 5, precludes the placement of the hand of the user in a position

consistent with the functional position during operation. For instance, Freeman requires gripping the instrument with the fingers, and does not utilize the hand, except that the fingers are attached to the hand. The grasping of the instrument utilizing the index and middle finger for stabilization and then using the thumb for actuation requires that the hand be held with the thumb in abduction and wrist in flexion. Thus actuation in use occurs at nearly 60-70 degrees of wrist flexion and is not within the parameters of the functional or ergonomic position of the hand, and can cause a significant degree of hand and wrist strain which may result in chronic joint stress leading to Carpal Tunnel Syndrome.

11. I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statement were made with the knowledge that willful, false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United State Code, and that such willful, false statements may jeopardize the validity of any patent issuing on the above identified proceeding.

DATED this 27 day of October, 2009.

W. Bradford Rockwell W. BRADFORD ROCKWELL